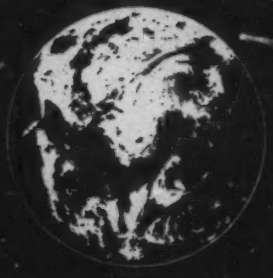
WORLD POPULATION



and

FERTILITY PLANNING TECHNOLOGIES

THE NEXT 20 YEARS

Summary

CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington, D.C. 20510

J952-12

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Foreword

This summary presents the major findings of the Office of Technology Assessment on world population growth and the present and prospective fertility planning technologies that will influence this growth in the future.

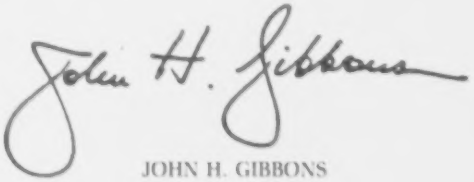
Rapid growth in population in the last 20 years is a result of improvement in health and agriculture technologies. Increased options for fertility change have also resulted from advances in science and technology. Because its mission includes foresight on emerging issues related to science and technology, OTA determined in 1978 that an objective analysis was timely and appropriate in providing Congress with improved insight in this area. The topic was discussed with Members of Congress and letters endorsing the study were received from the House Committee on Foreign Affairs, the House Committee on Science and Technology, and the former Subcommittee on Child and Human Development of the Senate Labor and Human Resources Committee. Permission to undertake the study was granted by OTA's Technology Assessment Board in response to a request by the Director.

The assessment covers current projections for population growth to 2000 and the implications of this growth; identifies the determinants of fertility change; reviews current reproductive research and contraceptive R&D; discusses the factors that influence the acceptance, distribution, and use of fertility planning technologies in LDCs; and examines U.S. funding arrangements in support of population assistance requests from LDCs.

Issues and options for Congress include:

- Federal support of contraceptive R&D;
- product liability and the contraceptive industry;
- effective patent life;
- export of non-FDA approved drugs;
- levels of funding for international population assistance; and
- distribution of population assistance funds.

The Office of Technology Assessment was assisted in the preparation of this study by an advisory panel of individuals representing demographic and family planning research, the pharmaceutical industry, health policy analysis, ethics and philosophy, and organizations holding differing views on current reproductive issues. Sixty-six reviewers drawn from universities, nongovernmental agencies, and the private sector provided helpful comments on draft reports. The Office expresses sincere appreciation to each of these individuals.



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World Population and Fertility Planning Technologies

Introduction

This assessment considers the probable impacts of specific fertility planning technologies on population growth. The influence of direct factors such as age at marriage and contraceptive use on population growth is relatively well understood. Less well understood are the indirect influences—the economic, sociocultural, religious, and political forces—that modify attitudes toward family size. Detailed examination of these indirect factors is beyond the scope of this study. Nevertheless, recognition of their importance in determining the use of fertility planning technologies underlies everything that follows.

Following World War II, the world experienced a sudden sustained drop in death rates which, combined with little change in birth rates, produced unprecedented growth in the world's population. Today, about 80 million people, the equivalent of an additional Mexico or Nigeria, are added to the planet every year.

More than 90 percent of this growth is in the developing world. In the United States and other more developed countries (MDCs), infant mortality is low and life expectancy exceeds 70 years, yet populations are stable or increasing only moderately because birth rates are low. In the less developed countries (LDCs), where infant mortality, although declining, is high, and life expectancy has not yet reached 55 years, birth rates remain high and populations are increasing, often at dramatic rates.

Rapid population growth in LDCs is a key factor in limiting the ability of these countries to raise their standards of living. Important obstacles to their socioeconomic development include limited resources, food distribution problems, high rates of debilitating disease and infant mortality, lack of proper sanitation, scarcity of investment capital, and shortages of educational facilities and work opportunities. But each of these barriers to a better quality of life in LDCs is intensified by the rapid pace of their population growth.

Because LDC governments that once dismissed rapid population growth as incidental to their well-being now actively seek help with their population problems, the United States and other MDCs provide population planning assistance as part of general developmental aid to countries who

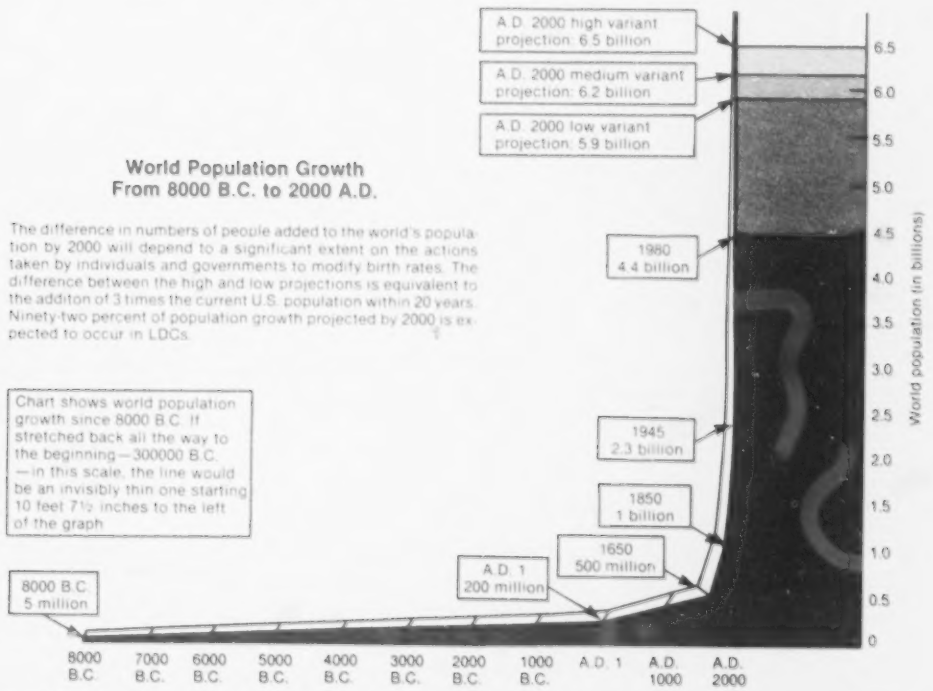
need and want help in reducing their birth rates. Such assistance has enabled many of these countries to achieve significant decreases in their population growth rates during the past decade, and there is now an international consensus that access to contraceptive services is a basic human right.

Findings and conclusions

Fertility is declining in most LDCs, but population growth is continuing at high levels because of the momentum for future growth initiated by the high birth rates and rapidly falling infant mortality rates of the recent past. More than 1 billion people will be in their peak reproductive years (ages 15 to 29) during the next two decades.

Even if growth rates continue their current decline, the world's population is expected to increase from 4.5 billion in 1981 to between 5.9 billion and 6.5 billion in the year 2000 (see fig. 1). Almost 92 percent of this growth will occur in LDCs. Growth will be greatest, according to current projections, in Africa (76 percent of the 1980 population added in 20 years), followed by Latin America (65 percent), and Asia (43 percent). But more of the increase in absolute numbers will occur in Asia (63 percent)

Figure 1.—World Population Growth From 8000 B.C. to 2000 A.D.


A.D. 2000 high variant projection: 6.5 billion
A.D. 2000 medium variant projection: 6.2 billion
A.D. 2000 low variant projection: 5.9 billion
World Population Growth From 8000 B.C. to 2000 A.D.
The difference in numbers of people added to the world's population by 2000 will depend to a significant extent on the actions taken by individuals and governments to modify birth rates. The difference between the high and low projections is equivalent to the addition of 3 times the current U.S. population within 20 years. Ninety-two percent of population growth projected by 2000 is expected to occur in LDCs.
Chart shows world population growth since 8000 B.C. If stretched back all the way to the beginning—300000 B.C.—in this scale, the line would be an invisibly thin one starting 10 feet 7½ inches to the left of the graph.
1980 4.4 billion
1945 2.3 billion
1850 1 billion
1650 500 million
A.D. 1 200 million
8000 B.C. 5 million
World population (in billions)
6.5
6.0
5.5
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0
8000 B.C.
7000 B.C.
6000 B.C.
5000 B.C.
4000 B.C.
3000 B.C.
2000 B.C.
1000 B.C.
A.D. 1
A.D. 1000
A.D. 2000

SOURCE: United Nations, *World Population Trends and Prospects by Country, 1950-2000: Summary Report of the 1978 Assessment*, New York, 1979, projections 1980-2000; Arthur H. Westing, "A Note on How Many Humans Have Ever Lived," *Bioscience*, vol. 31, 1981, pp. 523-524. Graph adapted from "Population Growth from 8000 B.C. to the present," Oct. 6, 1981, © 1981 by The New York Times Company. Reprinted by permission.

than in Africa (22 percent) or in Latin America (15 percent), simply because many more people already live in Asia. Three-quarters of all LDC growth is expected to occur in just 18 countries: India, China, Brazil, Nigeria, Indonesia, Bangladesh, Pakistan, Mexico, Philippines, Thailand, Vietnam, Turkey, Iran, Egypt, Ethiopia, Burma, South Korea, and Zaire, listed here in the approximate order of the magnitude of their projected growth.

The striking momentum of world population growth means that the number of births expected each year will increase despite falling fertility rates, because the number of people in the reproductive ages (15 to 44) is increasing.

Even when countries achieve replacement-level birth rates, stationary population growth—the stabilization of deaths and births at near equal levels—cannot be achieved until members of the largest age group (those between 0 and 4 years) reach old age some 60 years later.

Current declines in fertility are unevenly distributed among LDCs but many of those with the largest populations have achieved the greatest declines. China's birth rate has declined dramatically. Estimates of fertility decline between 1965 and 1981 range from 17 to 58 percent. South Korea's fertility has fallen by 34 percent, Colombia's by 34 percent, and Thailand's by 36 percent during the same period.

Significant fertility declines are usually associated with some or all of the following conditions that involve government policy and action with regard to population programs (ordering does not imply relative importance): 1) governmental policies that encourage and promote equal status and opportunities for women, higher age at marriage, and more equitable distribution of wealth and educational opportunities, all of which lead to a higher standard of living; 2) programs designed to bring about a decline in infant mortality; 3) a government policy with explicit goals for reduction of birth or population growth rates; 4) a strong commitment to population planning by the country's leaders; 5) a family planning organizational structure with executive power to mobilize more than one government sector and to coordinate with the private sector; 6) population program funding (usually both external and internal sources); 7) provision of a broad range of contraceptive methods; 8) sufficiently trained and motivated family planning program personnel; 9) population and family planning information, education, and communication (IEC) efforts that effectively reach all sectors of the population; and 10) direct or indirect incentives that encourage couples to limit the size of their families. The relative importance of these components is not known because country settings differ, and the nature of the country's developmental process and the level of certain key indicators (life expectancy, gross national product (GNP), nonagricultural labor force participation, literacy rates, etc.) affect the extent to which a program can succeed in lowering fertility. But the degree of political will and commitment and the extent of administrative capacity play major roles in determining the magnitude of fertility decline.

Most people in the developing world live in countries that now consider their rates of population growth higher than desirable and want help in achieving lower rates. Recent experience has shown that growth rates can be slowed, often with startling success, despite the momentum inherent in LDC age structures. Although other development factors influence fertility, both stronger family planning programs and more effective, safer, and easier-to-use contraceptive methods can make important contributions to slowing population growth in the next two decades.

If governments decide to take actions to reduce population growth in addition to those actions currently planned, the world's population in 2000 will be closer to the lower estimate of 5.9 billion than to the upper estimate of 6.5 billion. Even the low projection, however, means that today's 4.5 billion world population will increase by 1.5 billion in just 20 years. For the longer term, additional efforts undertaken now can be still more decisive because of the difference between the high and low projections for 2050: a world population of 8.4 billion instead of one of 12.4 billion, a difference nearly equal to today's global total.

Countries that wish to reduce their population growth rates have three options: raise mortality rates, encourage emigration (or discourage immigration), or reduce fertility rates. The first is morally untenable, and the second is not feasible over the long term because there are no countries left to accept vast numbers of immigrants. The only viable solution is to lower fertility rates. Many LDC governments have already decided to encourage this latter option; in the last 20 years, the proportion of the world's people who live in countries that provide support for family planning services has risen from about 10 percent to 90 percent.

Most LDCs face similar environmental and economic problems. In a number of these countries, the need to increase food and fuel production has led to significant environmental degradation through denuding of forests, transformation of productive land into desert, and waterlogging and salinization of irrigated land. The large balance-of-payments deficits and increased debts confronting most oil-importing LDCs in recent years have depressed their rates of economic growth, lowering prospects for meeting basic health care needs, and making the provision of jobs a formidable task.

The collective effects of these continuing environmental and social problems, exacerbated by rapid population growth, have led to increased international migration and political instability. U.S. interests are directly involved, for example, in present immigration pressures from Mexico, the Caribbean, South America, and Southeast Asia.

Rapid population growth is an intensifier of current environmental, food, energy, and resource pressures in LDCs, and its interaction with these problems is generating a new category of national security concerns. The implications of this interaction for national security, a term that is itself changing, remain largely unexplored.

Direct fertility determinants

Aside from indirect influences such as levels of socioeconomic development, education, and family size preferences, four factors have a direct and important impact on the number of births that will occur in the next 20 years: age at marriage, prevalence of breastfeeding, prevalence of induced abortion, and—the most significant—use of contraception.

Young age at marriage and near universality of marriage in the absence of widespread contraceptive use are important causes of high birth rates in many countries. High infant, child, and adult mortality in association with the social stigma attached to illegitimate births has necessitated very young age at marriage and maximum reproduction to ensure survival of the family lineage. Increases in age at marriage have contributed to fertility decline in many LDCs in recent years and may continue to do so in such areas as the Asian subcontinent, where age at marriage remains low.

Breastfeeding delays the return of ovulation after childbirth, sometimes for as long as a year or more. If large numbers of women breastfeed for long periods, a natural form of birth-spacing occurs that can cause a modest reduction in overall fertility rates. But breastfeeding is an important influence on fertility only in societies with high fertility rates. Breastfeeding is an imperfect individual contraceptive because the amount of protection against pregnancy that it confers is extremely variable. In LDCs, fewer women are now choosing to breastfeed, and many women are breastfeeding for shorter lengths of time.

The limitations of current contraceptive technologies and lack of access to their use cause many women in all parts of the world to seek induced abortion to terminate unwanted pregnancies. Induced abortion is a medically safe procedure when performed early in pregnancy by skilled personnel. But the risk of maternal death or serious complications increases greatly when it is performed by less skilled personnel in marginal facilities and when it is performed later in pregnancy. Rates of induced abortion are high in LDCs, even though its legal use is constrained in some countries by religious beliefs. It is rarely a preferred method of fertility planning, but is resorted to when other means are not available, or fail.

Of all the means available, contraceptive use is by far the most important in lowering fertility. On average, women are fecund (capable of bearing children) from age 15 to 45, about 30 years. In the absence of contraception and allowing for time spent pregnant and infertile (due to infertility following birth or to breastfeeding), and time not spent in union because of divorce or widowhood, a woman could expect to have an average of about 10 children. If reduction of fertility rates to those associated with population stabilization (about 2.2 births to each woman) is desired, it is necessary that some method of contraception be used for up to 25 years.

The major methods of contraception currently in use are:

- Sterilization—vasectomy in the male, and tubal ligation/occlusion in the female.

- Steroid hormones—combined (estrogen and progestin) or low dose progestin oral pills, or intramuscular, long-acting progestin injections. These synthetic steroids are given in different combinations and different doses, depending on the commercial product, but they act primarily by inhibiting ovulation through suppression of the hypothalamic hormones that stimulate the release of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the anterior pituitary. The synthetic steroids also cause endometrial changes that make the uterus inappropriate for implantation should breakthrough ovulation and fertilization occur. Other changes that contribute to the contraceptive effect include scant and thick cervical mucus, reduced sperm transport and penetration into the uterus, and altered sperm and ovum transport within the fallopian tubes.
- Intrauterine devices (IUDs)—the insertion of a foreign body, made either of an inert substance or impregnated with other materials (copper, progesterone). Although the IUD prevents implantation in some mammals, its mode of action is unknown in the human being. There are several possible modes of action, from interference with sperm transport, to interference with ovum transport, to interference with implantation in the uterus. There is also some evidence that IUDs lead to increased sperm damage and affect the motility of the ovum in the fallopian tube.
- Barrier devices—the condom for the male and the diaphragm and cervical cap for the female.
- Vaginal spermicides—high viscosity fluids that both kill sperm and block them from entering the cervical canal.
- Coitus interruptus—male withdrawal prior to ejaculation.
- Periodic abstinence (rhythm, natural family planning)—timed to avoid coitus near the day of ovulation.
- Postcoital douches—water or spermicidal solutions that flush out and kill sperm in the vagina.

Between now and the end of the century, more than 20 new or significantly improved technologies for contraception are expected to become available. Highly likely to be available by 1990 are:

- Steroid hormones: safer oral contraceptives, improved long-acting steroid injections, and two new methods of administration—steroid implants (e.g., capsules in the forearm) and steroid vaginal rings.
- IUDs: three improved types are anticipated. Improved versions of the copper-releasing IUD will be effective longer than current IUDs. Advanced versions of the progestin-releasing IUD may be as effective as the pill and require replacement only every 5 to 10 years. Postpartum IUDs, which can be safely inserted immediately following delivery without excessively high expulsion rates, will make IUDs available to large numbers of women in LDCs who otherwise might lack access to the medical personnel needed for insertion of other types of IUDs.
- Barrier devices for women: one-size-fits-all diaphragms, disposable diaphragms, spermicide-impregnated diaphragms, vaginal films, vagi-

nal sponges, vaginal rings that release spermicides, and cervical caps that can be left in place for weeks or months.

- Improved ovulation-detection procedures for use with periodic abstinence methods: a wide variety of biological and biochemical parameters are altered when a woman ovulates, and researchers are endeavoring to improve or simplify the physical tests that a woman can use herself to determine when she ovulates. Improved methods of evaluating changes in cervical mucus, hormones in urine or saliva, and basal body temperature would enable greater numbers of users of periodic abstinence to know with certainty when they could safely engage in sexual intercourse during the second half of the menstrual cycle without risk of pregnancy, although the prediction of ovulation is likely to remain problematic.*
- New hormonal methods: methods that would reversibly inhibit ovulation using synthesized agonists or antagonists to one of the hormones that controls ovulation, luteinizing-releasing factor (LRF).
- Drugs that induce menstruation: prostaglandin analogs that depend on uterine muscle contraction for their action. Administered as vaginal suppositories, these drugs can also induce abortion during the first 8 weeks of pregnancy in about 80 percent of cases.

Beyond 1990, fertility planning technologies may include a monthly pill or injection, antifertility vaccines for men and antipregnancy vaccines for women, ovulation prediction methods, simplified and reversible sterilization procedures, LRF analogs for self-administered induction of menses, and lactation-linked orals for women.

Most R&D on contraceptives has been conducted by MDC governments and the pharmaceutical industry. Prior to 1967, contraceptive R&D was financed largely through the private sector. In the 1970's, however, of funds spent worldwide on reproductive research and contraceptive development, private industry provided about 10 percent, and governments and philanthropic and nonprofit organizations provided 90 percent.

The market approval process of the FDA affects population planning assistance, because the U.S. Food, Drug, and Cosmetic Act prohibits pharmaceutical manufacturers from exporting drugs for uses not approved for marketing in the United States. This policy is based primarily on the premise that one standard of drug approval is necessary, and under this premise, the United States would be promoting a double standard if it exported drugs not approved for use in the United States.

The FDA approval process for all drugs averages 7.5 years. FDA requirements for the specific types of tests and test animals to be used in providing safety and efficacy data for contraceptives usually make the average length of the approval process for contraceptive drugs longer than for other drugs by about a year. This is because contraceptives are given to young, healthy individuals and can potentially be administered

*Such methods would also benefit couples with infertility problems by pinpointing the fertile period.

over a period of 30 years, whereas other drugs are usually used to treat diseases and/or are often administered only for a few weeks at most.

Drug patents run for 17 years, but effective patent life is shortened by the regulatory process. For oral contraceptives, however, shortened patent life has not affected the original manufacturers' abilities to retain a large share of the market even when prices were increased after the patent period had expired.

But expanding product liability has escalated costs and made the prediction of future costs uncertain for both the pharmaceutical industry and its insurers. As in the case of patent life, these difficulties are being experienced by all drugs (and products in general), but the contraceptive market has been especially affected by product liability problems.

Rising product liability costs and the ability of manufacturers to retain their market share even after patents expire signify higher prices for contraceptives and reduced purchasing power for family planning programs.

International population assistance

International population assistance evolved in response to growing awareness of the problems that accompany rapid population growth and to requests from LDC governments for technical assistance in addressing these problems. The purposes for which population assistance funds are expended include: 1) development of population planning policies appropriate to the recipient country; 2) contraceptive commodities; 3) systems for contraceptive distribution and use; 4) IEC activities; 5) research on the delivery of family planning services, on the development and application of improved or new contraceptive methods, on the social, economic, and cultural conditions that affect their acceptance and use, and on those social conditions that directly affect birth rates (e.g., age at marriage); and 6) the gathering, evaluation, analysis, and dissemination of demographic and other information.

Less than 2 percent of official development assistance from all MDC donors is currently allocated to population activities, a proportion that represents a small decline since 1970. The United States provides just under 4 percent of its total development assistance for international population activities.

In 1980, total resources (excluding China) committed to population and family planning programs in LDCs amounted to about $1.0 billion. Of this total, LDC contributions accounted for about $450 million, private sources about $100 million, and MDC sources about $450 million. Donor governments (including the United States) are the principal source of MDC assistance; funds are channeled: 1) through nongovernmental organizations (NGOs) such as the International Planned Parenthood Federation (IPPF) and Family Planning International Assistance (FPIA); 2) directly to LDC governments (bilateral assistance); and 3) through multilateral organizations such as the United Nations Fund for Population Activities

(UNFPA). Private sector donors channel money primarily through NGOs such as IPPF. MDC and private contributions arrive in LDCs as money, contraceptives, information, and technical assistance in developing and administering family planning programs and in collecting and analyzing population data. Agencies administering the largest amounts of population assistance are the U.S. Agency for International Development (AID), UNFPA, and IPPF.

The United States supports population assistance through two main channels, AID (Office of Population) and the World Bank. The World Bank receives moneys in the form of general development appropriations, about 1 percent of which are directed toward population projects. AID, in turn, channels funds bilaterally to LDC governments, multilaterally to UNFPA, and through private intermediary organizations, such as IPPF, FPIA, etc. World Bank support is exclusively loan assistance; AID programs are largely grant assistance but include some loans as well.

In fiscal year 1979, AID bilateral assistance totaling $48 million went to 33 LDC governments. NGOs channeled an additional $90 million from AID into technical assistance to 64 LDCs. Multilateral assistance totaling $30 million from AID went to UNFPA (26 percent of UNFPA's budget), which UNFPA in turn granted to 116 LDCs. IPPF channeled $22 million of AID funds (28 percent of its budget) to private IPPF affiliates in 88 LDCs.*

The amount of U.S. population assistance channeled through AID rose from $5 million in 1965 to $185 million in fiscal year 1979. This figure remained constant in 1980 and increased to $190 million in 1981 through continuing resolutions. The 1982 appropriation has been increased to $211 million; the authorization for fiscal year 1983 is $230 million.

Although the United States continues to provide the most population assistance to LDCs, its proportion of the total amount has decreased over the last 14 years. The United States provided 50 percent or more of all primary source assistance until 1974, when this proportion leveled off to about 40 percent, where it has remained. This decrease is largely due to increased contributions from other MDC donors, including the Scandinavian countries, Japan, and West Germany. In addition, the impact of inflation cut the 1981 funding level, in constant dollars, to $41 million below that of the peak year of 1972 ($121 million). The 1982 appropriation is $28 million below the amount required to maintain the 1972 level.

International population programs

Family planning programs contribute significantly to improved health of women and children and have made a substantial difference in accelerating the rate at which fertility declines. In countries with strong family planning efforts for which data are available, fertility declined an average of 30 percent between 1965 and 1975. This compares with declines of

*The usual funding level is about $12 million; this $22 million included forward funding to alleviate IPPF cash flow problems and the fiscal year 1980 appropriation was reduced accordingly.

about 4 percent in similar countries with weak family planning programs and 2 percent in countries with no programs. On balance, about 15 to 20 percent of the declines in fertility between 1965 and 1975 in 94 LDCs is attributable to the family planning component of population program effort.

The need for greater sensitivity to and knowledge of the role of the sociocultural factors that motivate people to adopt family planning is clear. Multifaceted programs that address relevant social, economic, and health needs along with delivery of family planning services are most likely to be successful.

The use of fertility planning technologies can substantially lower birth rates, but their availability and acceptability vary. Delivery systems may be inadequate or culturally inappropriate so that family planning services are in fact not effectively available. The contraceptive methods used in a particular country may not be the ones preferred but the ones available. People may become dissatisfied and discontinue the methods used because of side effects, the need for repeated application, costs, medical contraindications, contraceptive failure, and concerns about long-term safety. A realistic goal is for each country to have enough technologies appropriate for local conditions so that each individual has access to at least one method that meets his or her current needs. Improved and new technologies could enhance family planning effectiveness and efficiency by reducing side effects, permitting easier administration, and simplifying delivery system requirements.

At present, of 374 million couples of reproductive age in LDCs (excluding China), some one-fifth, or about 74 million, are using contraception. By 2000, there will be at least 638 million couples of reproductive age (889 million couples if China is included). Because about 80 percent of these couples would need to use some form of contraception if fertility were to approach replacement levels, the number of couples practicing family planning regularly and consistently would have to increase about sevenfold in the next 20 to 30 years.

Program costs per user currently range from $6 to $100 annually in LDCs, for an average of about $15 per user for an efficient family planning program (one that combines public and private sectors, provides access to voluntary sterilization, includes IEC activities, demographic data collection and analysis, and adequate infrastructure support). In order to increase current contraceptive use to the 80 percent of all couples of reproductive age necessary to approach replacement fertility levels, 300 million LDC couples (excluding China) would now have to be practicing contraception. Although contraceptive use is not expected to exceed 50 percent by 2000, if it were to reach the 80-percent level it would require, using the $15 cost per user per year, a minimum total international population support budget of $4.5 billion annually, including the contributions of LDCs. (This figure excludes China, where expenditure data are fragmentary.) Using the same assumptions of cost per user, and using 1980 dollars, the rise in numbers of couples in the reproductive ages

would increase this cost to about $7.4 billion in the year 2000. (Under this formula, the amount rises to $10.7 billion when China's childbearing-age population is added.)

Program emphasis will shift in coming years as LDC needs change. There will be greater emphasis on reaching rural populations, heavier reliance on private sector delivery systems, increased integration with other components of development, and decentralized approaches to meeting community-level needs. Management training will be crucial as the demand for services grows, as will increasing work opportunities for women in all sectors of development, including family planning programs.

Because LDCs consider the slowing of their population growth an urgent need and the lead time required to make new contraceptive methods available is relatively long, the methods that should be emphasized in the next decade are those already in hand and those that will become available in the next few years. Experience with family planning programs in LDCs indicates that if commitment is strong, if delivery systems are adequate and culturally acceptable, and if a broad range of methods is made available, the pace of fertility reduction can be enhanced. Although imperfect, currently available contraceptive methods can provide the basis for fertility reduction, but further biomedical research is critical to improving the safety, efficacy, and acceptance of contraceptives.

For policymakers concerned with modifying population growth, the most meaningful population information is the difference in numbers of people added to the world's population if governments do or do not take feasible actions to reduce birth rates in addition to those already under way. The actual amount attributable to additional governmental actions that reduce birth rates is neither accurately known nor explicitly stated by most demographic experts who make projections. There is general agreement, however, that if governments intensify current actions to reduce growth rates, the low variant projection is more likely to be achieved. The total difference between the high and low variants is sizable—650 million persons—and is equivalent to the addition of three times the current United States population in just 20 years.

Issues and options

The breadth of purpose of international population assistance, the range of its activities, and the variety of U.S. governmental involvement in these activities result in many issues of congressional interest. Not all of these issues require legislative action, and many can be examined through the congressional oversight process. In this section, the principal issues and related legislative options for: 1) Federal involvement in contraceptive R&D, and 2) international population assistance support are addressed.

In the biomedical research area, the issues center on the U.S. Government's key role in support of reproductive and contraceptive R&D and on reconciling how the United States regulates the drugs and medical devices

industries with the need to diffuse these technologies to countries that may have different risks or perceptions of risks.

Contraceptive technologies

The U.S. Government's role in the development and dissemination of contraceptive technologies is mediated through two avenues: 1) the R&D activities of the National Institutes of Health and AID; and 2) the regulatory policies of FDA. Peripheral to contraceptive technologies, but possibly affecting them, are U.S. patent laws and their interrelationships with FDA's regulatory process and the direction that product liability legal doctrines have taken in the United States.

THE ROLE OF THE U.S. GOVERNMENT IN CONTRACEPTIVE R&D

The Federal Government not only supports contraceptive R&D, but also regulates the drug and medical devices industries through FDA's market approval process in which efficacy and safety requirements must be met. The development and dissemination of contraceptive technologies thus can be influenced through Federal funding of contraceptive R&D, and through governmental actions that could stimulate or restrain expanded or renewed interest in contraceptive products by private industry.

ISSUE: Federal support of contraceptive R&D

In 1979, governmental agencies throughout the world provided approximately 80 percent of funding for reproductive research and contraceptive development. The United States provided nearly 60 percent of all funds, or about $89 million. Approximately 70 percent of worldwide expenditures were devoted to basic research, training, and institutional support; about 23 percent to contraceptive development; and approximately 7 percent to evaluation of current methods.

OPTIONS:

A. Sustain financial support of R&D at current levels.

If Congress continues to judge that governmental action is warranted to continue the development of improved contraceptives for use at home and abroad, the minimum action would be to sustain support of existing programs at current levels. Although the dollar amount for reproductive research and contraceptive development increased from $80 million in 1972 to $112 million in 1979, inflation has meant, in terms of constant dollars, a cut of about 20 percent from the 1972 funding level.

B. Substantially increase financial support.

Arguments for increases in contraceptive research include the following: Present contraceptive development programs may develop many useful new and improved contraceptives over the course of the next two decades if additional money is available. Because many LDCs are actively pursuing policies to reduce population growth and there is increasing concern in MDCs about the side effects of current fertility planning meth-

ods, there is a strong need for improved contraceptive methods both in the United States and abroad. The potential impact is enormous in terms of improved family planning effectiveness, reductions in numbers of unwanted pregnancies and induced abortions, improved maternal and family health, alleviation of human suffering, and opportunities for economic progress. Without such added investments, emergence of many new contraceptive products is likely to be either prevented or very substantially delayed.

Congress could authorize and appropriate more funds for the entire field of reproductive research, using the presently available funding channels, NICHD and AID. Alternatively, Congress may wish to increase funding only for contraceptive development. Added investments in this specific area are highly likely to produce payoffs in the form of useful new technologies. As total public funding for such development is currently less than $20 million annually, present funding levels could be significantly increased at relatively low cost. An additional $20 million annually in this specific field could have a substantial impact.

The budget of AID's Office of Population also could be augmented and earmarked or recommended for contraceptive development, which would enable AID to increase funding for both the three U.S.-based international contraceptive development programs and other groups that could contribute to this endeavor.

Increases in NICHD's budget would need to be earmarked for the Contraceptive Development Branch. Such action would greatly increase the volume of goal-oriented R&D being conducted under contract by NICHD. This action would contribute directly to the development of new contraceptives for U.S. use and indirectly to the work of international programs seeking to develop and introduce new contraceptives in LDCs.

C. Reduce financial support.

Although it could be argued that industry invests little in contraceptive R&D because government funds are available, and that one impact of this option would thus be increased industry participation, such factors as product liability are major deterrents to greater industrial participation in contraceptive R&D. For basic reproductive research, the additional factors of longer time for return on investment and greater risk further deter industrial participation in fundamental research.

A reduction exclusively in NICHD's budget would rapidly result in a discontinuation of research by many U.S. research centers now working in this field under NICHD support. Much of the Nation's safety research on contraceptive methods currently in use would also be eliminated. At least initially, the direct effect on the U.S.-based contraceptive development programs to which AID contributes (IFRP, PARFR, and ICCR) would be minimal, as they are not funded by NICHD. But because these other programs utilize basic research and goal-oriented research findings that emerge from NICHD-funded projects, over the long term their prospects

for successful development of new methods could be reduced significantly.

A reduction exclusively in AID's contraceptive development program likely would be detrimental for at least three of the four nongovernmental contraceptive development and dissemination programs.

STIMULATE THE INTEREST OF PRIVATE INDUSTRY IN CONTRACEPTIVE R&D

Most of the numerous factors that might stimulate more private industry interest in contraceptive R&D concern removing apparent disincentives against developing and marketing of contraceptive products. But as these factors also involve major issues in their own right, trying to change these factors to promote contraceptive R&D quickly impinges on other substantial interests. Hence, although options for some factors are discussed here, it should be kept in mind that the effects of these changes would reach beyond contraceptives to other drugs and other products.

ISSUE 1. Product Liability and the Contraceptive Industry

According to representatives of companies actively researching new contraceptive products, product liability is as great a negative factor in making a business decision regarding new contraceptives as meeting the FDA requirements for safety and efficacy.

The primary effect on a manufacturer from product liability is financial; i.e., compensation for claimants and defense of claims. A secondary effect is the adverse publicity accruing to the product and its manufacturer. Because of increasing frequency of claims and escalating size of successful judgments against contraceptive manufacturers, pricing of liability insurance has become so uncertain that insurers are either withdrawing from the field, mandating that manufacturers self-insure larger and larger amounts of first-dollar costs, or placing contraceptive drugs and devices in special categories of risk separate from product liability insurance for the manufacturer's other products.

As liability costs are business expenses that are incorporated into the price of the affected product, manufacturers may be increasingly reluctant to devote research and development efforts to products such as IUDs. Once the sale is made, there is less opportunity to recoup liability costs, as sales are not as frequent and continuous as they would be for oral contraceptives. With the latter, liability costs can be passed on, which may explain in part the large price increases of oral contraceptives (discussed next) in comparison with other drugs. Thus, product liability may be affecting not only the propensity of private industry to develop new contraceptives but also the kinds of contraceptives to be developed in the future.

ISSUE 2. Effective Patent Life

The current process through which drugs and medical devices are cleared for commercial distribution and sales takes a number of years. However, in order to protect its interest in the potential new product, a

company must apply for and be granted a patent long before the product has been approved by FDA. Drug patents run for 17 years, but it takes an average of 8.5 years for a contraceptive drug to clear the regulatory process, cutting its effective patent life to less than 9 years. Whether this situation inhibits the development of new drugs and medical devices is not clear.

Wyeth Laboratories and Ortho Pharmaceutical share approximately 70 to 80 percent of the U.S. market for oral contraceptives. Wyeth's patent on norgestrel is still in effect, but the patent on norethindrone expired in 1973. Since the patent expiration, only Mead-Johnson and Lederle have entered the market, and Lederle no longer markets its oral contraceptive. No generics (nonbrand name drugs) have entered the market. The Pharmaceutical Manufacturers Association also reported in August 1980 that oral contraceptives had the greatest price increases of all classes of pharmaceuticals in the periods 1969 to 1979 (187 percent) and 1978 to 1979 (23.7 percent), as compared to only a 37.4 percent increase in price during 1969 to 1979 and a 6.5 percent increase in 1978 to 1979 for a sample of over 1,000 drugs. Although other factors (e.g., product liability) may be at work, shortened patent life has not had a significant effect on the oral contraceptive market. After patents have expired, prices have remained high and new firms have not been able to enter the market on a competitive basis.

ISSUE 3. Export of Non-FDA Approved Drugs

The market for U.S. manufacturers of contraceptives could be expanded if the law on the export of non-FDA approved drugs were changed.

Current law prohibits the export of drugs for uses that are prohibited in the United States. Two categories of drugs are at issue: 1) drugs unevaluated for use; and 2) drugs evaluated but not approved for use. There are some exceptions to the drug exportation ban; e.g., investigational drugs can be exported for investigational purposes, provided that the importing country's government has approved such imports. In addition, medical devices not approved for marketing in the United States can be exported if: 1) they conform to the laws and specifications of the importing country; and 2) their export is not considered by the Secretary of Health and Human Services to be contrary to the public health and safety of the importing country.

Changes in the export provision of non-FDA approved drugs have been considered by Congress. In the 96th Congress a bill adopting the medical devices export law for drugs was passed by the Senate but died in the House of Representatives.

OPTIONS

A. Keep the status quo, where drugs not approved for marketing in the United States cannot be exported to other countries but medical devices can be exported under certain conditions.

By keeping the status quo, Congress prevents the foreign marketing of drugs that have not been adequately tested or whose safety has not been established by U.S. standards.

However, the relative risks and benefits of a drug are not the same for people in LDCs, where health conditions, including the risks of pregnancy and childbearing, are quite different from those in the United States. Further, the wide range of contraceptives available to U.S. women may not be available to women in LDCs, a factor that affects the risk/benefit assessment of a particular contraceptive. Thus, the United States may be depriving women in LDCs of drugs that would have a greater benefit than risk for them.

B. Adopt the medical devices export law for drugs.

As in the case of medical devices, non-FDA approved drugs could be exported, provided that the specifications and laws of the importing country were met, and the Secretary of HHS determined that the importing country's public health and safety were not compromised.

C. Adopt the medical devices export law for drugs, and add one or more of the following provisions:

1. Require that the risk/benefit analysis for an unapproved drug take into consideration conditions of the drug's use (and other health risks) to individuals in the importing country

This provision is based on the assumption that the risks and benefits of a given drug can change from country to country. Some advocates of this provision believe that a risk/benefit analysis of a drug should be based on data actually obtained in the importing country and in response to requests from that country. Determination of a drug's benefits would be based on the prevalence and severity of the target medical condition, and safety assessments could consider such items as the extent to which the drug user could be monitored for adverse reactions. Other user conditions—e.g., nutritional status—that could affect a drug's safety and efficacy could also be studied.

Instead of actually collecting data from clinical trials conducted in the importing country, it may be more feasible to adjust data collected from other countries to reflect user conditions and disease prevalences in the importing country. It is very difficult to collect data from a sufficient number of women within any given country when low-incident, but very important, medical events are to be assessed.

2. Establish industrial standards of conduct.

Procedures could be developed in which officials—and perhaps the public—in importing countries could be informed of the risks, benefits, and costs of the drugs they wish to import. Written verification of such an informed consent process, signed jointly by company executives and importing country officials, could be filed with the Secretary of Health and Human Services (HHS). Violation of that document could serve as a basis for withdrawal of approval.

D. Develop international standard-setting mechanisms on the use, safety, and effectiveness of contraceptive drugs and devices.

If modifications of existing export laws on drugs along the lines of the current medical devices export law (options 2 and 3) are adopted, such international standards would be helpful to the Secretary of HHS in determining whether or not the importing country's public health and safety are compromised.

INTERNATIONAL POPULATION ASSISTANCE

Many LDCs now actively seek population assistance and their requests for population assistance have risen to the point that donor agencies can meet only a fraction of current requests for such aid.

ISSUE 1. Level of Funding

OPTIONS:

A. Reduce financial support.

Reduced support from the United States for population programs would force LDCs to reduce their programs, cut back on supplies that require foreign exchange, eliminate training programs, and probably decrease program outreach to rural and other hard-to-reach areas. Because the momentum for population growth already exists, spending for population programs deferred now would still be necessary at higher funding levels because of inflation, loss of trained personnel, and duplication of start-up costs. The capability of LDCs to finance their own family planning programs through such promising avenues as commercial retail sales (CRS) programs would be postponed. (CRS programs provide oral contraceptives, condoms, and spermicides at low cost and can effectively extend to hard-to-reach areas. However, they require substantial initial funding for bulk procurement of contraceptives, subsidizing of retail prices, and technical assistance in the establishment of backup medical services.) Also, if the U.S. level of support were to be decreased now, self-sufficiency of LDCs in population planning and progress in economic development might be further delayed, resulting in: 1) deteriorating social and economic conditions including increased death rates in LDCs; 2) need for significant future increases in general economic developmental assistance from MDCs to LDCs; or 3) if the United States were to abstain from future increases in economic developmental assistance, widening of the economic chasm between MDCs and LDCs, with all of the political implications that are associated with these differences.

Overall, U.S. cuts would disrupt the current working balance among private organizations, intergovernmental agencies, and government donors, with particularly adverse effect on the private agencies that are likely to suffer major reductions yet are often the most cost effective. Under current budgets, AID and the multilateral donors cannot meet current commitments. With further cuts, many countries and agencies would have to reconsider their ability to implement effective programs.

The U.S. Government, as the largest single donor to international population assistance, has been able, to some degree, to coordinate population assistance efforts and influence the direction of funding. A reduction in population assistance funds would reduce U.S. influence on program strategies and design.

B. Increase financial support.

Congress has in fact increased its appropriation from $190 million in fiscal year 1981 to $211 million in 1982; $230 million has been authorized for 1983. These current and potential increases represent a significant step and underscore the importance of population assistance at a time when many high priority social programs are being cut. However, inflation has reduced the purchasing power of these funds to below that of the total amount provided for population funding in the peak year of 1972 ($121 million, or about $239 million in 1982 dollars). At a time of rising requests for assistance, the AID population commitment is decreasing in purchasing power.

AID's fiscal 1982 budget is about $200 million below levels of documented need and insufficient to the point that: 1) most AID-supported projects and programs will receive less than the funds needed to satisfy demand for family planning services or otherwise function optimally (this includes inability to meet shortfalls at UNFPA, IPPF, and other major private voluntary organizations); 2) there will be few new initiatives in Africa (where governments are now beginning to ask for assistance) and the Near East; and 3) projects are being terminated prematurely, before recipient countries become self-sufficient.

UNFPA's 1982 calendar year budget of $135 million represents a shortfall of $40 million to $100 million. The $40 million represents the gap between available funds and established needs for ongoing programs and commitments previously made. The $100 million includes new programs that have been requested and merit funding, but for which funds are not available. However, a much larger number of countries now wish population assistance, and there has been a 20 percent increase in couples of childbearing age in LDCs since 1972.

Excluding China, only 20 percent of couples of reproductive age are currently using contraception in LDCs. Efficient programs cost an average of $15 per user annually (new programs can cost as much as $100 per user). Many countries are only beginning to implement family planning programs so start-up costs are very high. If fertility is to fall to replacement levels, contraceptives must be used by about 80 percent of couples in the childbearing ages. The growth in the population, the need for increased use of fertility planning methods, and higher costs of programs that cannot be fully implemented until LDCs themselves can contribute more support all argue for major incremental increases in population assistance in the coming years.

One approach to steady incremental increases in funding would be to meet the recommendation of the International Conference of Parliamentarians on Population and Development held in Colombo, Sri Lanka in 1979. Delegates representing 58 countries unanimously called for a total annual allocation of $1 billion in international population assistance (exclusive of LDC commitments) by 1984.

More recently, at the International Conference on Family Planning in the 1980's held in April 1981 in Jakarta, Indonesia, participants from 76 African, Asian (including China), Latin American, and Middle Eastern countries joined representatives of major international agencies in calling for a rapid increase in overall national and international expenditures for population and family planning programs to $3 billion annually.

Assuming that the United States wishes to maintain its 40 percent share of the total assistance budget and that other MDCs and private sources increase their contributions, the goals set by these international representatives might be attained, although the timing is likely to be delayed. If the United States were to increase its contributions by 30 percent per year (assuming an annual inflation rate of 15 percent), its contributions could keep pace with inflation and incremental funding would be available for increasing needs. The United States would thereby maintain its leadership position in population assistance and would contribute significantly to meeting requests from LDCs for assistance with a problem most of these countries now view as high priority.

ISSUE 2. Distribution of Population Assistance Funds

Present channels and content of population assistance programs reflect both the priorities of the assistance agencies and the needs of LDCs. A change in the present distribution system would affect the type of aid available and hence would have different impacts on different regions.

Because of differences among regions, wide-ranging approaches are required. In general, Asia's primary needs are for efficient and effective services delivery to very large rural populations, a large volume of supplies, and additional training in health care and program management.

In Latin America, some governments are reluctant in the face of religious and conservative opposition to give rigorous support to family planning programs, but public demand for family planning services is growing rapidly. As a consequence, support for private agencies and expansion of family planning within health care systems are increasing.

In the Middle East, the limitation of opportunities beyond childbearing for women is a major barrier to fertility change. Expansion of government and private services, and of broad social programs, is needed. The continuation of innovative efforts by private population and family planning agencies to change perceptions of the role of women is crucial.

Birth rates in some countries in Africa are the highest in the world, but few African countries have formulated policies that make a direct connection between their serious economic and social problems and rapid pop-

ulation growth. As most of these countries do, however, favor the provision of family planning services in the context of maternal and child health activities, emphasis should be on support for family planning as a component of health programs. Improved collection and analysis of demographic and other data would make an important contribution to increased understanding of the magnitude of population growth and its impact on economic development and the environment. Expansion of the role of existing private voluntary agencies would facilitate delivery of family planning services and improvements in maternal and child health.

There is thus a major difference between Asia, for example, where governmental programs are established but where support is needed to make them comprehensive and effective, and Africa, where there is much less appreciation of the implications of rapid population growth and less governmental commitment to extend family planning services widely.

These broad generalizations mask the variability that exists among countries, which is at least as great as that among regions. Different countries have different cultural values and development goals and thus require different forms of assistance. Different forms of government and different political alliances also make some forms of assistance more appropriate to one country than another.

Technical assistance and commodities for population planning and family planning programs are currently channeled through several major international agencies and many private nongovernmental agencies. The largest agencies, AID, UNFPA, IPPF, and the World Bank provide technical assistance in varying degrees in the areas of family planning services (including commodities); information, education, and communication; institutions and training; research and evaluation; policy development; and data collection.

Each agency tends to have different emphases and priorities within a broad range of support activities. For example, UNFPA provides technical assistance for basic population data collection, and channels assistance for family planning services primarily through health ministries incorporated into maternal and child health programs. AID is the largest supplier of commodities and places strong emphasis on family planning services delivery. IPPF emphasizes family planning services delivery in private sector clinic settings. Because each agency has different emphases and countries have different priorities, the agencies can cooperatively tailor their support to individual country needs.

About 28 percent of AID funds are currently dispensed to the multilateral agencies (UNFPA and IPPF), 26 percent are dispensed bilaterally, and 46 percent dispensed to and through private intermediaries and organizations. Changes in present proportions of assistance would have uncertain effects on the balance that has been achieved among these agencies and there are no compelling reasons for considering changes at this time. Given current shortfalls, duplication of efforts is not an issue, but if funds are increased, efforts to promote greater coordination among

agencies at administrative and country levels would need to be examined more closely.

Additional issues for congressional oversight

- Establishment of a single congressional mechanism for continued oversight of population issues.
- Review criteria for determining which countries receive population assistance and channels through which assistance is funneled.
- Review of U.S. priorities and restrictions in addressing global population issues, such as prohibition of aid to China.
- Consideration of ways to accelerate the pace of self-sufficiency in LDCs and encourage greater participation of the private sector in LDCs.
- Address the factors of product liability suits, shortened patent life, and FDA's export provisions on drugs, which may be inhibiting the development, manufacturing, and marketing of contraceptives and other medical products.

NOTE: Copies of the full report "World Population and Fertility Planning Technologies: The Next 20 Years" can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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GPO : 1982 O - 84-588

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OTA-HR-158

FEBRUARY 1982